4. DISCUSSION OF SAFETY AND EFFECTIVENESS

A. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Model No. /Names:	MedX HOME (Console and 1 – 2 SLD Accessories – MedX 601)
Classification:	Lamp Infrared, Heating Category ILY Physical Medicine Device, 21 CFR 890.5500 (Class II)
Predicate Device:	MedX 1000 Series Console & LED Accessories (uses the MedX 600 LED Accessory)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description of the Device

MedX HOME console powers one to two SLD Accessories. It uses the MedX 600 accessory, called the MedX 601 SLD accessories for the HOME unit and a smaller console, based on the MedX 1100 Console.

The MedX HOME console powers one to two SLD accessories. The MedX HOME Console includes semiconductors and assembly, electronics, controls, liquid crystal display, front panel and labels. The front panel contains the membrane switch with command keys to enter data and select options.

The port on the right side of the console is dual purpose. First, with the use of a programming key, the clinician can access software to sets the specific treatment parameters for individual patients. Without this key plugged in the software is not visible.

The second purpose of the port is for the patient to plug in the SLD accessories. This only provides access to a limited area of the software, allowing the patient to select one of potentially 5 different treatment numbers associated with a pre-programmed treatment.

The left side of the console panel has the ON/OFF switch and the plug for the electrical outlet.

The liquid crystal display provides 4 lines of 15 characters each line for prompting, options, and selections.

The main label is located on the rear panel of the console.

The MedX HOME uses the MedX 600 SLD accessory, called the MedX 601 for this purpose, to generate therapeutic heating, to comply with the heating category, ILY requirements.

The SLD accessory use 633 nm and 870 nm superluminous diodes to produce the heat required for topical heating, resulting in the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, and minor pain and stiffness associated with arthritis.

The SLD device generates 500 mW of power to produce therapeutic heat. The accessories are powered by the console and can be set to pulse from 1 – 2000 pulses per second. The console automatically turns itself off after the set treatment time has been delivered.

No national body has established safety or performance standards for infrared lamps in the US or Canada. The device is designed in accordance with UL 2601, and meets the requirements of this standard in Canada with field inspections completed by Entella on all equipment prior to shipping.

The products have been:

- Health Canada – Medical Device Branch – Therapeutic Devices Directorate approved (Canada)
- ISO 9001 and ISO 13485
- QSR compliant

Technology Characteristics Summary

The technological characteristics are based on the predicate device – K020017.

MedX HOME has been tested in the areas of mechanical, electrical, controls, and thermal safety, environmental conditions and electromagnetic compatibility, temperature control and irradiation distribution patterns. The MedX HOME has been found to be safe in all of the above areas for the intended use referenced in this submission.

Discussion of Non-Clinical and Clinical Data

Internal testing has demonstrated the ability of MedX HOME to warm the surface temperature to therapeutic heating. No clinical research was conducted for this specific 510(k) submission.

Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for MedX HOME indicates that they meet design and performance functional requirements. Clinical practice and academic research demonstrate that therapeutic heating from an infrared lamp can be used successfully to provide topical heating for the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles, for muscle spasms, minor pain and stiffness associated with arthritis. The proposed device meets the requirements of international and US medical electrical equipment standards for safety, and key performance and safety requirements.

B. DEVICE SPECIFICATIONS

The MedX HOME Console

The MedX HOME Console powers the SLD accessories that produce the therapeutic heating. The console supports the electronics, controls and labels. See *Appendix 1(a) for the MedX HOME Main Board, 1 (b) the MedX HOME Daughter Board and 1 (c) the Block Diagram of the MedX HOME system.*

The front panel contains the membrane switch with four buttons for Select/Start, menu, pause/clear and < and > keys. The liquid display window has 4 lines with 15 characters per line. The main label is located on the console rear panel. The ON/OFF switch is on the left side of the console with the electrical plug input. The right side of the console has a dual purpose port. When the clinician plugs in the set-up key, software is accessible to select specific treatment parameters, including treatment time and pulsing for up to 5 different treatments (A, B, C, D, and E) and number of days the unit will function prior to requiring re-setting by the clinician. When the SLD accessory is plugged into the port and the console is turned ON, only the pre-set treatments (A through E) appear on the LED display. (*Figure 1 - MedX HOME Console Front View and SLD Accessories (Front and Back Views).*

The MedX HOME SLD Accessory

The MedX HOME powers and controls the MedX 601 SLD accessory, consisting of 9 - 633 nm visible red SLD and 40 – 870 nm infrared SLDs. The MedX HOME SLD accessory treatment area or radiant surface is 19.4 cm^2. The enclosure material is made of ABS plastic, with the radiant surface covered with a polycarbonate window. *(Figure 1* - The MedX 601 Accessory Radiant Surface and Back Views are included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAY - 5 2005

Ms. Anita Saltmarche RN, BScN, MHSc
VP of Clinical and Scientific Affairs
MedX Health, Incorporated
3350 Ridgeway Drive Unit 3
Mississauga Ontario, Canada L5L 5Z9

Re: K050022
Trade/Device Name: MedX Home
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: April 15, 2005
Received: April 20, 2005

Dear Ms.Saltmarche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number:

Device Names: MedX HOME

INDICATION FOR USE

Indication for Use

The MedX HOME System Console System is an infrared lamp system, as per 21 CFR 890.5500. The energy emitted provides topical heating when heat is indicated *"for the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness, and the relaxation of muscles; for muscle spasms, and minor pain and stiffness associated with arthritis".*

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (X) OR Over-the-counter Use - ___
(Optional Format 1-2-96)

(Division Sign-off)
Division of General Restorative Devices

510(k) Number:

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050022